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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/824,005 | 04/14/2004 | John H. Griffin | P-082-US3 | 5957 |
| 27038 | 7590 | 09/02/2004 | EXAMINER | |
| THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080 | | | HABTE, KAHSAI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/824,005 | GRIFFIN ET AL. | |
| | Examiner | Art Unit | |
| | Kahsay Habte, Ph. D. | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 13-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 13-30 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is unfused 1,3-diazines (moiety formulae XI, XII, and XIII), classified in class 544, subclass 295, 322, 330, 333, and 335.
 - II. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is pyrrollopyridine (moiety formula XV), classified in class 546, subclass 113.
 - III. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is piperidines with additional imidazole (moiety formula XIV), classified in class 546, subclass 210.
 - IV. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is pyrazole (moiety formula IX), classified in class 548, subclass 364.1, 364.4, 364.7, 365.1, and 371.7.
 - V. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is indolone (moiety formula XXVIII), classified in class 548, subclass 466, 467, and 486.

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- VI. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is oxygen containing 10-membered ring (moiety formula XXVI), classified in class 549, subclass 354.
- VII. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is quinone derivative (moiety formula VI), classified in class 552, subclass 261.
- VIII. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is nitriles (moiety formula XXVII), classified in class 558, subclass 390, 389, 396, and 408.
- IX. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is amides (moiety formulae XVI, XIX), classified in class 564, subclass various.
- X. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is bicyclic ketone (moiety formula VIII), classified in class 568, subclass 327.
- XI. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is ether (moiety formula XXIV), classified in class 568, subclass 589.
- XII. Claims 13-30 (in part), drawn to compounds of formula I where the moiety ligand is miscellaneous non-heterocyclic (X, XX, and XXIX), classified in class various, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Groups I-XII are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of L in formula I do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. The nature of the ring (heterocyclic, non-heterocyclic, fused, spiroconnected, etc), nature of heteroatoms in heterocyclic rings (O, N, S, etc), the size of the rings (5-, 6-, 7-, 8-, 9-membered), of each Group is different one from the other. Each group has its own class and subclass. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

If applicants elect one of the inventions in Groups V-XII; a tentative election species is required.

A telephone call was made to Ms. Joyce Cohen on August 10, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Note, for a classification purposes, if diverse ligand fall in different classes, the class that has higher Group number dominates. For example if a ligand at one end falls in Group I and the ligand at the other end falls in Group IX, the compound will be classified in Group I.

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

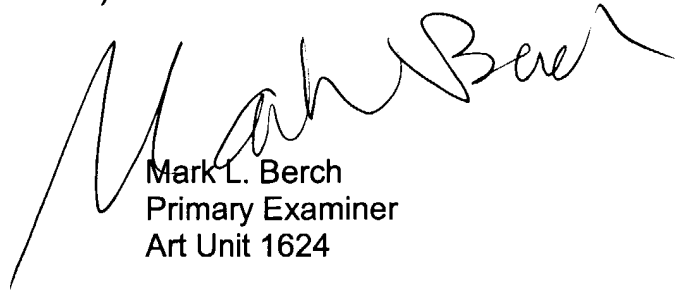
For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
September 1, 2004